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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,851	05/28/2002	Horst Rapp	HMN 2 0021	8437

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/22/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/031,851

Applicant(s)

RAPP ET AL.

Examiner

Shaojia A Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

This application is a 371 of PCT/EP00/06997 which claims foreign priority to German 199 34 585.6 under 35 U.S.C. 119(a)-(d). The certified copy has been filed with the instant Application. It is noted that PCT/EP00/06997 and German 199 34 585.6 are in German, no translation into English.

Applicant's preliminary amendment in Paper No. 7, submitted July 10, 2003 is acknowledged, wherein claims 1-19 have been amended as to remove the recitations "Use" in the claims and claim 20 is newly submitted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-20 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling the instant compounds for treating particular skin diseases disclosed in the specification (page 3), does not reasonably provide enablement for treating any "diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases and disinfection".

It is noted that "disinfection" is not considered to be a disease state.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set

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forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method of treating any “diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases and disinfection”.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on treating any diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses any “diseases of the skin and mucous membranes, organs, tissues except for retroviral HIV diseases and disinfection”, a great

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numbers of skin diseases, which may be involved various, many possible, and different etiologies. Thus, the skilled artisan would view that the treatment of all skin diseases by administering the particular compound herein, i.e., tosylchloramide, is highly unpredictable.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects and toxicity generated by administering tosylchloramide for treating any skin disease herein.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

It is noted that the specification merely provides the working examples for treating several particular skin diseases at page 10-14 of the specification, e.g., itching caused by mosquito bites (Example 4 at page 10), Herpes Labialis, neurodermatitis with herpes superinfection (Example 5 at page 11).

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad treatment of any skin diseases recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of treating any skin diseases recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent

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protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test the instant compound for treating any skin diseases encompassed in the instant claims, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations, "their derivatives" and "decomposition products" in claim 1 render claims 1-7 and 9-20 indefinite. The recitations, "their derivatives" and "decomposition products" are not defined in the specification. Hence, one of ordinary skill in the art could not interpret the metes and bounds as to "their derivatives" and "decomposition products", since one of ordinary skill in the art could not interpret the metes and bounds of the patent protection desired as to "their derivatives" and "decomposition products". Thus, it is unclear what would be encompassed as "their derivatives" and "decomposition products" in the claim.

The recitation, "disinfection" in claim 1 render claims 1-3 and 6-20 indefinite. The recitation, "disinfection" is not defined in the specification. As indicated above, "disinfection" is not a disease state. Moreover, one of ordinary skill in the art could not interpret the metes and bounds as to "disinfection". Thus, it is unclear what "disinfection" would encompass in the claim.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3-6, 8, and 10 recite the broad recitation and the claims also recite "may be", "in particular", and "such as" which are the narrower statements of the range/limitation.

Claim Objection

Claims 1-19 are objected to for minor informalities. The expression "administration" but missing "to the said skin" or "the infected area of skin" in the claims is considered informal. Appropriate correction is required.

Note that the recitation, "A medicament" in claim 20 will be examined as a pharmaceutical composition for the following reason. According to the ordinary and customary meaning of "medicament" provided by a dictionary: "An agent that promotes recovery from injury or ailment; medicine", and medicine is also defined as "a drug or other agent used to treat disease or injury" (see the definitions of medicament and medicine provided by the American Heritage Dictionary, Second College Edition, 1982, page 781, PTO-892), Thus, the recitation, "A medicament", would be interpreted herein as a pharmaceutical agent, a drug, or a pharmaceutical composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-13, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wakeman (3,317,540, PTO-1449 submitted January 23, 2002).

Wakeman discloses that tosylchloriaamide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair

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and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see col.1 and col.3 lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloriaamide(s) in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O?W or W/O-emulsion (see col. 2 line 32 to col.3 38). Wakeman's method inherently treats the instant particular skin diseases, since Wakeman's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Wakeman anticipates claims 1-6, 9-13, 17, and 20.

Claims 1-10 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 197 12 565 (PTO-1449 submitted January 23, 2002).

DE 197 12 565 discloses that tosylchloriaamide(s) and its known derivatives such as Chloramin T are useful in a pharmaceutical composition by topical administration to skin broadly and hair and thus useful in treating skin diseases herein (see Table at page 5 and claims 1-16). DE 197 12 565 also discloses the effective amounts of the pharmaceutical compositions of tosylchloriaamide(s) (see Table at page 5 and claims therein). The method of DE 197 12 565 inherently treats the instant particular skin diseases, since the method steps therein are same as the instant method

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steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, DE 197 12 565 anticipates claims 1-10, and 20.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Vandeveld et al (WO 91/07876, PTO-1449 submitted January 23, 2002).

Vandeveld et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandeveld et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms

herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20). Vandeveld's method inherently treats the instant particular skin diseases, since Vandeveld's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254,

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195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Vandeveld anticipates claims 1-20.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Harwardt et al (DE 41 37 544, PTO-1449 submitted January 23, 2002).

Harwardt et al discloses that tosylchloriaamide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloriaamide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4). Harwardt's method inherently treats the instant particular skin diseases, since Harwardt's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Moreover, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3d. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it related to the claimed invention herein.

Thus, Harwardt anticipates claims 1-20.


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In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.



S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
September 12, 2003
